CHAMPVA POLICY MANUAL

CHAPTER: 2
SECTION: 31.8
TITLE: COMBINED LIVER-KIDNEY TRANSPLANTATION

AUTHORITY: 38 CFR 17.270(a); 17.272(a)(1)(4)(13)(14)(59) and 17.273

RELATED AUTHORITY: 32 CFR 199.4(e)(5)

I. EFFECTIVE DATE

A. November 12, 1992.

B. November 1, 1994, for hepatitis C.

C. December 1, 1996, for hepatitis B.

II. PROCEDURE CODE(S)

A. CPT codes: 47133-47136, 50320-50365, and 50380

B. ICD-9-CM codes: 50.51, 50.59, and 55.69

III. POLICY

A. Combined liver-kidney transplantation (CLKT) requires pre-authorization.

B. All medically necessary services and supplies related to CLKT are covered when the transplant is performed at a Medicare-certified, TRICARE-certified, or TRICARE-certified pediatric consortium liver transplantation center. All of the following criteria must be met:

1. beneficiaries must have concomitant, irreversible hepatic and renal failure;

2. beneficiaries must have exhausted more conservative medical and surgical treatments for hepatic and renal failure;

3. beneficiaries must have a realistic understanding of the range of clinical outcomes that may be encountered; and

4. beneficiaries must have plans for long-term adherence to a disciplined medical regimen that are feasible and realistic.

C. Transplants performed for beneficiaries suffering from hepatic failure resulting from hepatitis B or C are covered.

D. For a properly pre-authorized patient, medically necessary services and supplies related to CLKT are cost shared for:

1. evaluation of a potential candidate's suitability for CLKT whether or not the patient is ultimately accepted as a candidate for transplantation;

2. pre- and post-transplant inpatient hospital and outpatient services;

3. pre- and post-operative services of the transplant team;

4. the donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and donated organ to the location of the transplantation center;

5. maintenance for the viability of the donor organ is covered after all existing legal requirements for excision of the donor organ has been met;

6. blood and blood products required for the transplantation;

7. donor costs;

8. FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary and in accordance with nationally standards of practice within the general medical community (i.e., proven);

9. the complications associated with the transplant procedure, including inpatient care, management of infection, and rejection episodes;

10. the periodic evaluation and assessment of the successfully transplanted patient;

11. air ambulance may be cost shared when determined to be medically necessary (see Chapter 2, Section 32.1, *Ambulance Services*).

12. hepatitis B and pneumococcal vaccines for patients undergoing transplantation are covered; and

13. DNA-HIA tissue typing for determining histocompatibility is covered.

IV. POLICY CONSIDERATIONS

A. Pre-authorization or retrospective authorization of CLKT is required. When pre-authorization was not obtained, but patient meets (or at date of transplantation would have met) patient selection criteria, and if the transplant facility is (or was at date of transplantation) a Medicare-certified, TRICARE-certified, or TRICARE-certified pediatric consortium liver transplantation center, then CHAMPVA benefits may be extended.

B. In those cases where the beneficiary fails to obtain pre-authorization, benefits may be extended if the services or supplies otherwise would be covered but for the failure to obtain pre-authorization. If pre-authorization was not obtained, the claim will be reviewed to determine whether the beneficiary's condition meets the clinical criteria for the transplantation.

C. Claims for services and supplies related to the transplant will be reimbursed based on billed charges. Effective August 1, 2003, combined liver-kidney tranplantation (CLKT) shall be paid under the assigned DRG based on the patient's diagnosis. All services related to CLKT prior to August 1, 2003, shall be reimbursed per the cost-to-charge payment system (seeChapter 3 Section 6.3, *Cost-To-Charge (CTC) Payment System).*

D. Charges from the donor hospital will be cost shared on an inpatient basis and must be fully itemized and billed by the transplant center under the name of the CHAMPVA patient (see Chapter 2, Section 31.1, *Donor Costs*).

E. Claims for transportation of the donor organ and transplant team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost shared on an inpatient basis. Scheduled or chartered transportation will be cost shared.

F. Acquisition and donor costs are not considered to be components of the services covered under the DRG. These costs must be billed separately on a standard UB-92 claim form under the name of the CHAMPVA patient.

G. When a patient is discharged (less than 24 hours) due to circumstances that prohibit the authorized transplant, such as the available organ is found not suitable, all charges will be cost shared on an inpatient basis. When admitted, the expected stay was for more than 24 hours.

V. EXCEPTIONS

A. CLKTs performed on an emergency basis in an unauthorized liver transplant facility may be cost shared only when the following conditions have been met:

1. the unauthorized center must consult with the nearest authorized liver transplantation center regarding the transplantation case, and

2. It must be documented by the transplant team physician(s) at the authorized liver transplantation center that transfer of the patient (to the authorized liver transplantation center) is not medically reasonable, even though the transplantation is feasible and appropriate.

B. This policy does not apply to beneficiaries who become eligible for Medicare coverage for just renal disease. This policy applies only to those individuals suffering from concomitant hepatic and renal failure. Coordination of benefits with Medicare is not required for CLKTs.

C. Benefits may be allowed for patients with a history of alcohol or other substance abuse if:

1. there is evidence of sufficient social support to assure assistance in alcohol rehabilitation and immunosuppressive therapy following the operation;

2. the patient has been abstinent (for at least six months prior to transplantation is recommended), it is the responsibility of the transplant facility to determine if the patient is a transplant candidate;

3. there is no evidence of other major organ debility (i.e., cardiomyopathy); and

4. there is evidence of ongoing participation in a social support group, like (Alcoholics Anonymous).

VI. EXCLUSIONS

A. Services/supplies provided at no cost or if the beneficiary (or sponsor) has no legal obligation to pay. This includes expenses or charges that are waived by the transplantation center. [38 CFR 17.272(a)(1)]

B. Services/supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program, unproven procedure). [38 CFR 17.272(a)(13)]

C. Services/supplies or devices, even those used in lieu of the transplants, when determined to be related or integral to an investigational or experimental (unproven) procedure (see Chapter 2, Section 16.5, *Experimental/Investigational (Unproven) Procedures*). [38 CFR 17.272(a)(14)]

D. Pre- or post-transplant nonmedical expenses (i.e., out-of-hospital living expenses, to include, hotel, meals, privately owned vehicle for the beneficiary or family members). [38 CFR 17.272(a)(4)]

E. The transportation of a living organ donor or cadaver. [38 CFR 17.272(a)(59)]

F. Administration of an investigational or experimental (unproven) immunosuppressant drug that is not FDA approved or has not received CHAMPVA approval as an appropriate "off label" drug indication (see Chapter 2, Section 30.8, *Immunosuppression Therapy*).

G. Combined liver-kidney transplantation is excluded when any of the following contraindications exist:

1. there are significant systemic or multisystemic diseases (other than hepatorenal failure) which limits the possibility of full recovery and may compromise the function of newly transplanted organs,

2. the patient has active alcohol or other substance abuse history (see Exceptions of this policy), or

3. the malignancies have metastasized to or extend beyond the margins of the liver and/or kidney.

END OF POLICY